

Notice of Allowability

Application No.

10/776,733

Examiner

Bin Shen

Applicant(s)

GOLLER ET AL.

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 9/18/2006.
2. ☒ The allowed claim(s) is/are 2-6.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert P. Hoag on 11/16/2006.

The application has been amended as follows:

Amend the claims as follows:

Cancel claim 1.

New claim 6 has been added in place of claim 1.

--6. (New) Method for simultaneous determination of mammalian cell proliferation inhibition activity and cell toxicity activity of a test substance in a single sample of cells comprising

a) contacting a proliferating mammalian cell sample that is present in a predetermined amount with said test substance in at least two different predetermined concentrations;

b) contacting said cell sample with a first fluorescence dye that specifically stains either dead cells or viable cells and optionally with a second fluorescence dye staining all cells;

c) adding to said cell sample a predetermined amount of latex particles with a size ranging from about 1 to about 20 μm and optionally staining said latex particles with a third fluorescence dye;

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d) determining ratio of the amount of total cells to the amount of latex particles in said cell sample;

e) determining the ratio of step d) and by flow cytometric analysis in said sample

- the number of dead cells or viable cells to total cells by fluorescence light emitted by said first fluorescence dye at a first wavelength;

- the number of total cells per volume by scatter light at a first angle or alternatively by fluorescence light emitted by said second fluorescence dye at a second wavelength;

- the number of latex particles per volume by scatter light at a second angle or alternatively by fluorescence light emitted by said third fluorescence dye at a third wavelength;

f) and determining the cell proliferation inhibition activity and toxicity of said test substance by comparing the ratio of viable cells to total cells and the ratio of dead cells to total cells at different concentrations of the test substance.--

In Claim 2, line 1, "1" has been deleted and replaced by --6--.

In Claim 3, line 1, "1" has been deleted and replaced by --6--.

In claim 3, line 2, after "and" in the second occurrence, --total--has been inserted.

In Claim 5, line 1, "1" has been deleted and replaced by --6--.

Enclosed are revised Figures 2 & 3.

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

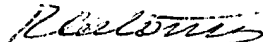
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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

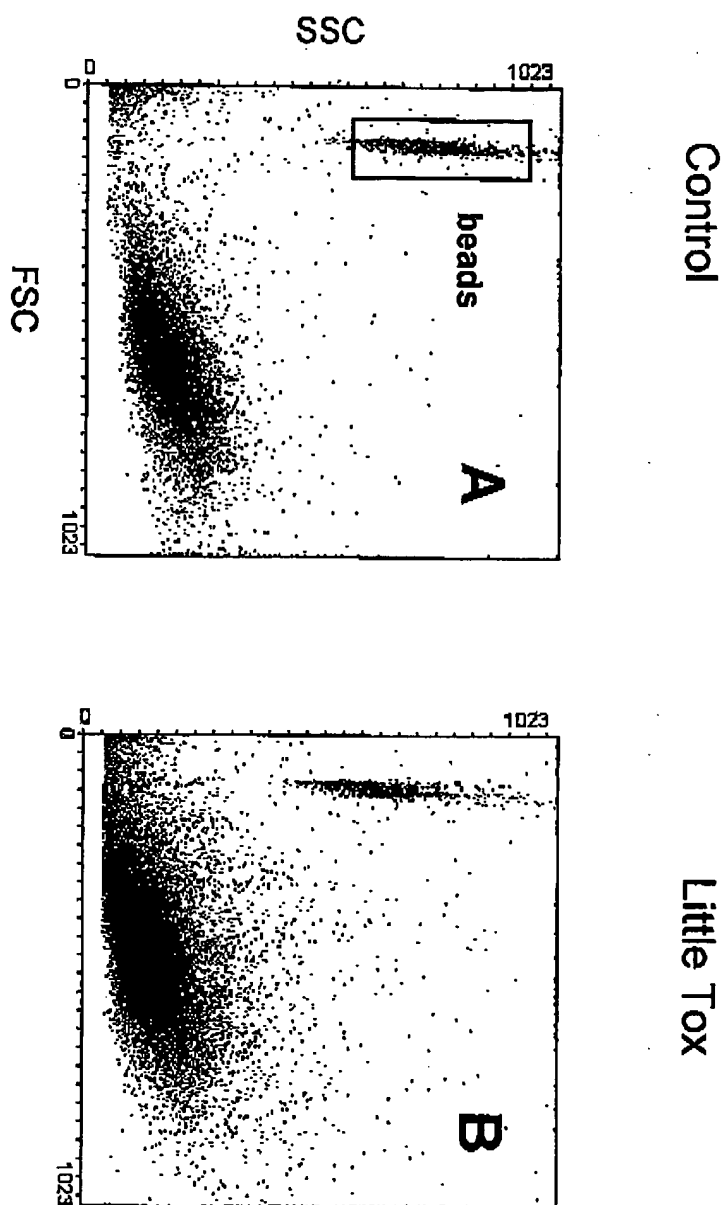

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200

B Shen

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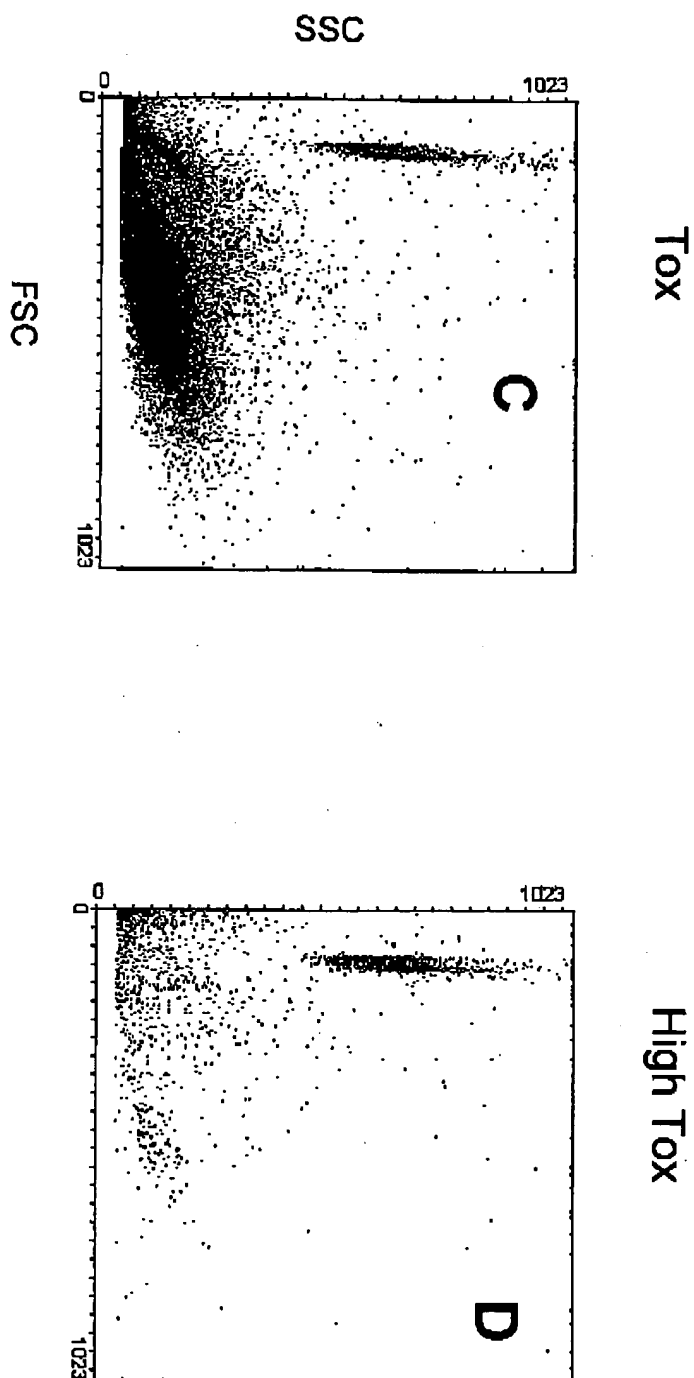
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Fig. 2 – Part 1: CD34 cell count and cytotoxicity analysis by FACS



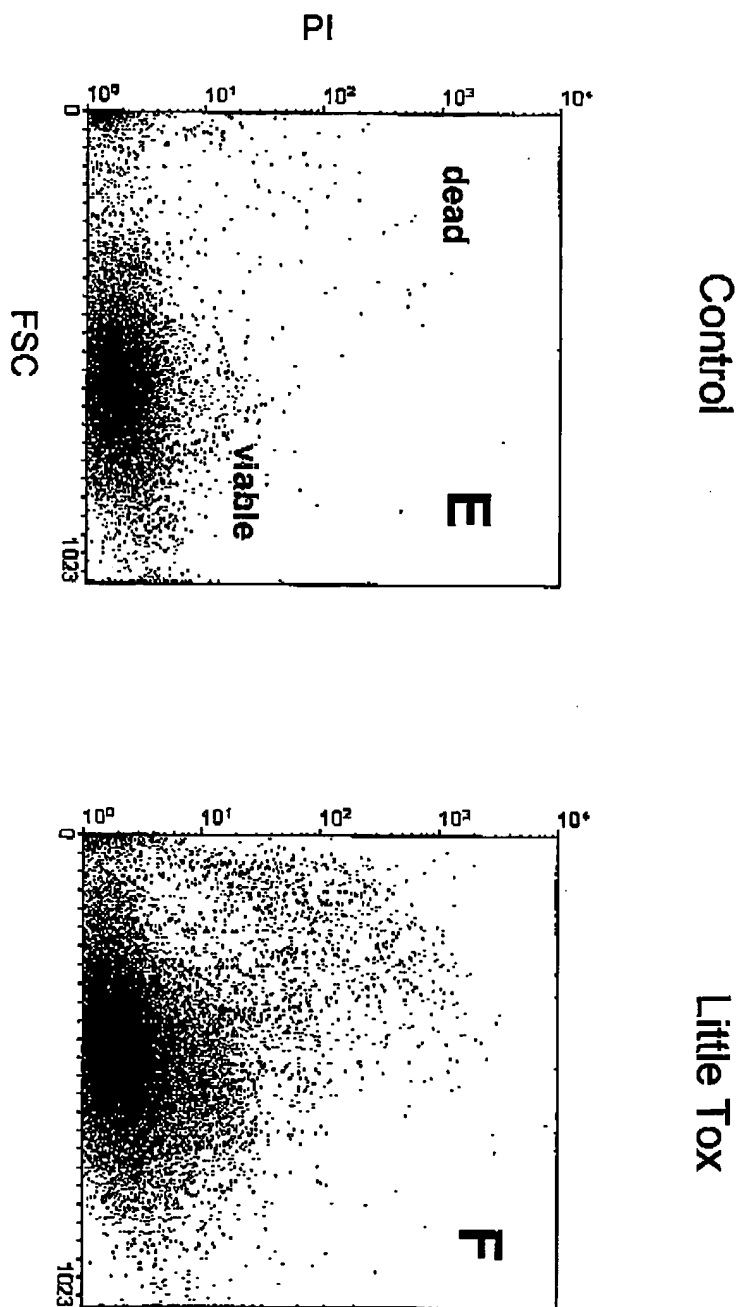
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Fig. 2 – Part 2: CD34 cell count and cytotoxicity analysis by FACS



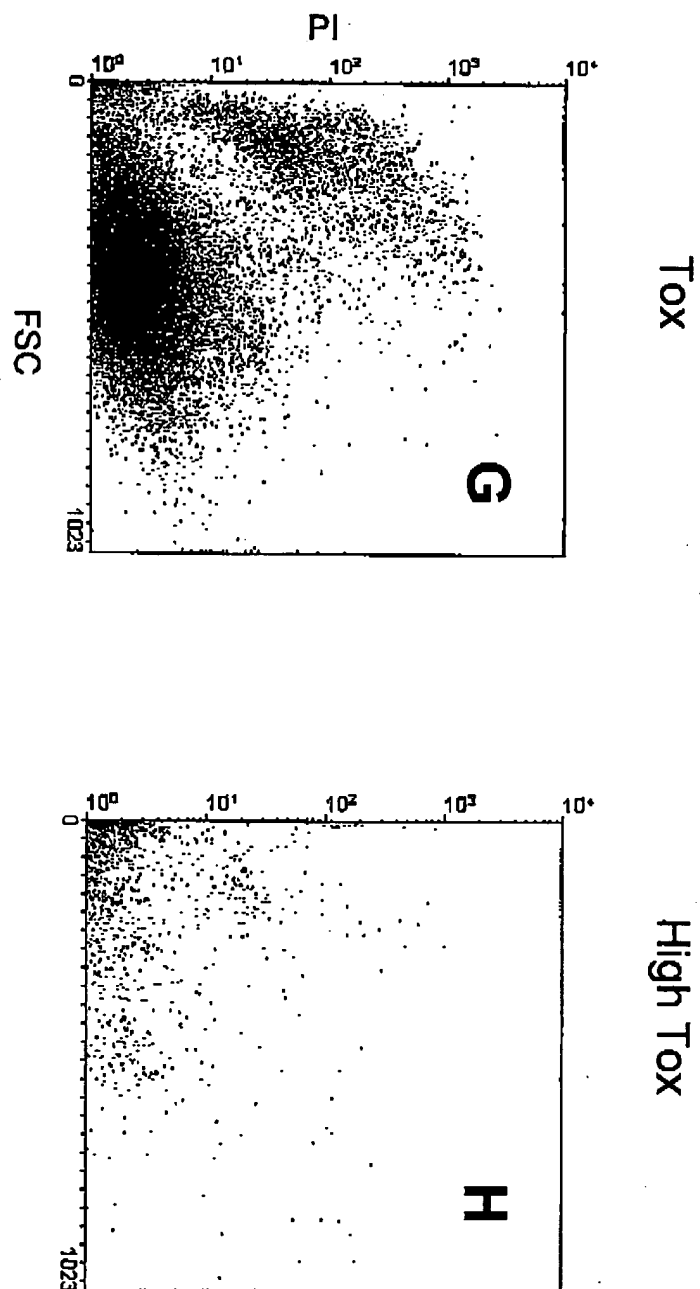
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Fig. 2 – Part 3: CD34 cell count and cytotoxicity analysis by FACS



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Fig. 2 -- Part 4: CD34 cell count and cytotoxicity analysis by FACS



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Fig. 3

